K010024

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Oridion

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4.0 510(k) Summary

Product name
Proprietary: O_2/CO_2 Nasal Filterline
Common: Nasal Cannula Gas sampling line for capnograph with integrated Oxygen Administration means for simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation.

Establishment registration number
Establishment registration number: 8044004

Establishment Address:
ORIDION MEDICAL 1987 LTD.
HAR HOTZVIM SCIENCE BASED INDUSTRIAL PARK
POB 45025
91450 JERUSALEM, ISRAEL

Device Listing Fda Form 2892:
A 733250

Product classification
The O_2/CO_2 Nasal Filterline is classified as Class II according to 21CFR868.1400 (73CCK)

INTENDED USE:

The intended use of the O_2/CO_2 Nasal Filterline is to conduct a sample of the adult/pediatric subject's breathing from the subject, via a nasal cannula, to a gas measurement device (capnograph) while simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation. The device is to be used with monitors using Oridion Microstream technology.

DEVICE DESCRIPTION

The common product name for this device is Nasal Cannula Gas sampling line for capnograph with integrated Oxygen Administration means for simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation. The complete device is a combined device consisting of two devices, as described below, integrated to simultaneously perform the function of both devices

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The CO_2 gas sampling nasal cannula is used with a Microstream capnograph (carbon dioxide analyzer 21CFR 868.1400). There is a nasal cannula at one end of the device for connecting to the patient's nose, a Microstream sample tube with a female Luer lock on the other end for connecting to the capnograph. The CO_2 Cannula is identical to the Oridion CO_2 Nasal Cannula K980325.

Attached and integrated with the CO_2 nasal cannula is another device for simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation. The O_2 cannula has a tube with a standard O_2 connector bushing on the end for connecting to a normal O_2 supply. The O_2 device is classified as class I according to 21CFR868.5340.

PREDICATE DEVICE

There are three predicate devices:

- The Adult predicate device is the Hospitak disposable CO_2 Gas sampling/Oxygen delivery Cannula K915228
- The Pediatric predicate device is the Salter Laboratories Model 4701 CO_2 Gas sampling/Oxygen delivery Cannula
- The CO_2 sampling predicate device is the Oridion Nasal Filterline K980325. The CO_2 section of both the Adult and pediatric Cannulas are identical to the Oridion CO_2 Nasal Cannula

SUBSTANTIAL EQUIVALENCE:

The Oridion O_2/CO_2 Nasal Filterline is a combination device that combines a CO_2 sampling nasal cannula with a O_2 supply nasal cannula

- The Oridion Adult O_2/CO_2 Nasal Filterline is essentially equivalent to the Hospitak disposable CO_2 Gas sampling/Oxygen delivery Cannula K915228.
- The Oridion Pediatric O_2/CO_2 Nasal Filterline is essentially equivalent to the Salter Laboratories Model 4701 CO_2 Gas sampling/Oxygen delivery Cannula

Clinical Study Report Summary and Conclusion:

- A comparison of performance and efficacy of the Oridion O2/CO2 Adult Nasal FilterLine (DUT) and Hospitak MAC-SAFE™Nasal Cannula (CAT.NO.368) (Comparison Device (CD), an accessory marked in the USA, clearly shows substantial equivalence between the two nasal cannulas .
- A comparison of performance and efficacy of the Oridion O2/CO2 Pediatric Nasal FilterLine (DUT) and the Salter Laboratories Pediatric Model 4701 Nasal

Cannula (Comparison Device (CD)), an accessory marked in the USA, clearly shows substantial equivalence between the two nasal cannulas.

- For certain features the results showed superior performance for the O_2/CO_2 Nasal FilterLine (DUT).

- From the patient data collected in this study we can observe that the O2/CO2 Nasal FilterLine (DUT) :
  - ❖ Effectively delivers Oxygen.
  - ❖ Maintains accurate CO_2 recording while simultaneously delivering Oxygen.

  In a manner that is substantially equivalent to the predicate devices.

- Hence supporting the claim for substantial equivalence to the Hospitak O_2/CO_2 Adult Nasal Cannula, the Salter Laboratories O2/CO2 Pediatric nasal cannula and the Oridion CO_2 nasal Filterline which are legally marketed in the USA.

Patient Data Summary:

- Patient data in this report (Appendix A3) is presented to support the claim of substantial equivalence of the O_2/CO_2 Nasal FilterLine (DUT) to **Hospitak** O_2/CO_2 Nasal Cannula (CD) and the Salter Laboratories O_2/CO_2 Nasal Cannula.

- Patient data presented was collected using a combined sidestream capnograph and pulse-oximeter – NPB-75 FDA File Number K964239.

- Patient data presented was collected in several clinical environments under professional medical supervision as described below (Appendix A)

- Patient population taking part in the clinical investigation of the efficacy of the O2/CO2 Nasal FilterLine (DUT) was adult and pediatric. The data pertaining to the dilution test was collected from healthy adult subjects according to the Clinical Investigation Plan (Appendix A Document DD-005603).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2001

Mr. Sanford Brown
Oridion Medical 1987 Ltd.
P.O. Box 45025
Jerusalem 91450
ISRAEL

Re: K010024
O_2/CO_2 Nasal Filterline
Regulatory Class: II (two)
Product Code: 73 CCK
Dated: December 12, 2000
Received: January 3, 2001

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

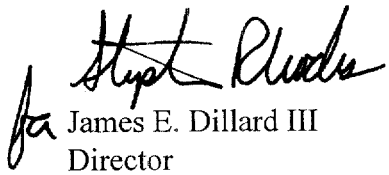
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Oridion

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6.0 INDICATIONS FOR USE FORM

510(k) Number (if known): K010024

Device Name:
O_2/CO_2 Nasal Filterline

Indications For Use:
The O_2/CO_2 Nasal Filterline is intended for use with a Microstream capnograph, to sample exhaled gas via a nasal cannula. The O_2/CO_2 Nasal Filterline can be used to simultaniously provide supplemental oxygen near the nose and mouth for inhalation. The O_2/CO_2 Nasal Filterline is for use to treat adults and pediatric patients

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010024